

sidered in its entirety and in the setting in which it was used, created the false and misleading impression that the article was a safe, adequate, and effective treatment for simple irritations of the vaginal tract; and under 502 (j), in that the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling.

The complaint further alleged that if the defendants were forced by an injunction to refrain from using the existing labeling on interstate shipments of the article, the defendants would not discontinue interstate distribution of the article but would, unless enjoined, continue to ship the article in interstate commerce without labeling stating the dosage for the article and without labeling stating the conditions and purposes for which the article was intended; and that, in such case, the article would be misbranded under 502 (f) (1), in that its labeling would fail to bear adequate directions for use because of the omission from its labeling of the dosage for the article and because of the omission from its labeling of statements of the conditions and purposes for which the article was intended.

**DISPOSITION:** 12-23-54. The defendants having consented, the court entered a decree of injunction perpetually enjoining the defendants from introducing into interstate commerce the article, or any other article of similar composition, which was misbranded under 502 (a), 502 (f) (1), and 502 (j).

**4582. Vaginal suppositories (11 seizure actions).** (F. D. C. Nos. 36839, 36840, 37064, 37083, 37084, 37092, 37119, 37274, 37368, 37563, 37611. S. Nos. 43-171 L, 43-173 L, 47-896 L, 67-955 L, 74-102/3 L, 79-885 L, 79-888 L, 80-067 L, 81-080 L, 86-437 L, 6-261/2 M, 14-247 M.)

**QUANTITY:** 11,048 boxes at Los Angeles, Oakland, Sacramento, and San Francisco, Calif., New Orleans, La., Indianapolis, Ind., Houston, Tex., St. Louis, Mo., and Cleveland, Ohio.

**SHIPPED:** Between 3-19-54 and 12-13-54, from Chicago, Ill., by Dr. J. A. McGill Co.

**LABEL IN PART:** (Box) "Contents 6 Suppositories \* \* \* Orange Blossom Suppositories \* \* \* Alum—Borax—Petrolatum \* \* \* Dr. J. A. McGill Co. \* \* \* Chicago 16, Ill."

**ACCOMPANYING LABELING:** Leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

**LIBLED:** Between 6-16-54 and 1-17-55, N. Dist. Calif., S. Dist. Calif., E. Dist. La., S. Dist. Ind., S. Dist. Tex., E. Dist. Mo., N. Dist. Ohio.

**CHARGE:** 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment of diseases of the vaginal tract which are manifested by irritation of the vaginal tract; and, 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions—Remove tinfoil and at bed time insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

**DISPOSITION:** Between 6-29-54 and 3-3-55. Default—destruction.